EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
NORTHWESTERN DIVISION

EDWIN R. BANKS,	
Plaintiff,	
v.	**Case No. 5:20-cv-0565-LCB**
ALEX AZAR,	**OPPOSED**
Defendant.	

DECLARATION OF JAMES PISTORINO IN SUPPRT OF MOTION FOR SUMMARY JUDGMENT

I, James Pistorino, declare:

1. I am over the age of 18, have never been convicted of a felony, and I make the following statements of my own free will.

2. I am a graduate of Duke University (B.S.C.S) and the Duke University School of Law (J.D.), and a partner at Parrish Law Offices. I am a member of the State Bars of California and Texas as well as the Patent Bar and am admitted in numerous district and appellate federal courts across the country. I have been practicing law (primarily federal litigation) for more than 20 years.

3. Attached, as Exhibit 1, is a true and correct copy of excerpts from the Office of Medicare Hearings and Appeals Case Processing Manual.

4. Attached, as Exhibit 2, is a true and correct copy of a Notice of Hearing dated April 17, 2019.

5. Attached, as Exhibit 3, is a true and correct copy of a Notice of Hearing dated May 13, 2019.

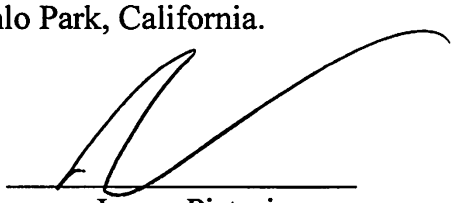
6. Attached, as Exhibit 4, is a true and correct copy of a Notice of Hearing dated May 14, 2019.

7. Attached, as Exhibit 5, is a true and correct copy of a pre-hearing brief sent on April 15, 2019.

8. On information and belief, the Secretary did not appear at the hearing held on May 15, 2019.

9. Attached, as Exhibit 6, is a true and correct copy of a decision issued by ALJ Scott Peterson on May 28, 2019.

10. I declare under penalty of perjury, except for statements made upon information and belief, that the statements made herein are true and correct and if called upon as a witness I would testify thereto. Executed this 14th day of May, 2020 at Menlo Park, California.



James Pistorino

OMHA Case Processing Manual

Chapter 14 SCHEDULING AND NOTICING FOR PREHEARING CONFERENCES AND HEARINGS

Section	Title
14.0	Chapter overview
14.1	Prehearing conferences
14.2	When to schedule a hearing
14.3	Determining the time and place of the hearing
14.4	Scheduling the hearing
14.5	The notice of hearing
14.6	Responses to the notice of hearing
14.7	Rescheduling the hearing
14.8	Amended notices of hearing
14.9	Canceling the hearing
14.10	Scheduling supplemental hearings

14.0 Chapter overview

(Issued: 09-28-18, Effective: 09-28-18)

This chapter describes the process for scheduling prehearing conferences and hearings, the activities that must be completed before a hearing is scheduled, and the circumstances where a hearing is required. This chapter also identifies the parties, potential parties, and participants to whom notices must be sent, and how to address responses to these notices and any objections or requests that may be made by the recipients. Finally, this chapter discusses when a hearing may be rescheduled or canceled with appropriate notice, and when a supplemental hearing may be necessary.

Caution:	When taking the actions described in this chapter, ensure that all PII, PHI, and Federal Tax Information is secured and only disclosed to authorized individuals (internally, those who need to know).

Send the notice and appropriate enclosures to:

Part A or Part B QIC reconsideration (non-MSP)

- The **appellant**(s);
- Each **non-appellant party**, unless the party:
  1) Did not participate in the reconsideration (for example, did not also file a request for reconsideration);
  2) Was not found liable for the items or services at issue after the initial determination and
  3) Will not be found liable at the OMHA level;

Note:	Non-appellant parties include both the provider and beneficiary when the appellant is a Medicaid State agency.

- The **AdQIC**;[63]
- CMS or any CMS contractor that elected **participant** status; and
- Any other CMS component or contractor involved in processing the claim or an appeal of the claim that the ALJ believes would be beneficial to the hearing (for example, the MAC, or a RAC or UPIC that reviewed the claim).[64]

Part A or Part B QIC reconsideration of MSP recovery against beneficiary

- The **beneficiary** (if represented, both the **beneficiary** and **representative**);
- The **AdQIC**;
- CMS or any CMS contractor that elected **participant** status; and
- Any other CMS component or contractor involved in the recovery that the ALJ believes would be beneficial to the hearing (for example, the CMS Benefits Coordination and Recovery Center (BCRC)).[65]

[63] CMS has designated the AdQIC to receive notices of hearing in Part A and Part B appeals of QIC reconsiderations. *See* 42 C.F.R. § 405.1020(c)(1).
[64] 42 C.F.R. § 405.1020(c)(1).
[65] 42 C.F.R. § 405.1020(c)(1).

EXHIBIT A-2

Department of Health and Human Services
Office of the Secretary

RECEIVED APR 22 2019
19-112

OFFICE OF MEDICARE HEARINGS AND APPEALS

Arlington Field Office
2511 Jefferson Davis Highway, Suite 3001
Arlington, VA 22202
571-457-7200 (Main)
571-457-7270 (ALJ Gulin Team)
703-603-1812 (Fax)
866-231-3087 (Toll Free)

April 17, 2019

E. BANKS
128 HUNINGTON CHASE DR
MADISON, AL 35758-6921

NOTICE OF HEARING

Appellant:	**E. BANKS**
Beneficiary:	**E. BANKS**
Medicare Number:	*******8912A**
Date(s) of Service:	**08/12/2018–08/12/2018**
OMHA Appeal Number:	**1-8428973391**
Administrative Law Judge:	**Jeffrey Gulin**

A hearing in the above appeal is scheduled for:

Hearing Date:	**Wednesday May 15, 2019**
Hearing Time:	**10:15 AM Eastern Time**

You are scheduled to appear by:
- ☒ Telephone
- ☐ Video-Teleconference (VTC)
- ☐ In-Person

You must call 844-892-5247 at the designated time of the hearing and enter 8163217362 when asked for a passcode or collaboration code. Failure to call at the scheduled time will be considered a failure to appear for the hearing.

What do I do next?

You must respond to this notice within 5 calendar days of receipt. You are encouraged, but not required, to use the enclosed *Response to Notice of Hearing* (form OMHA-102) when responding. If you are a party to the appeal, your response must indicate whether you plan to attend the scheduled hearing, or whether you object to the proposed time and/or place of the hearing. If applicable, you must specify who else from your organization or entity plans to attend the hearing and in what capacity, and list any witnesses who will be providing testimony.

If you are an employee of CMS or a CMS contractor and wish to attend the hearing as a participant, your response must indicate that you plan to attend the hearing and specify each individual who plans to attend.

What if I object to the type of hearing?

If you are a party to the appeal and you object to the type of hearing scheduled, please complete section 6 of the enclosed *Response to Notice of Hearing*, and indicate what type of hearing you would prefer (if you are also requesting to change the time of your scheduled hearing, see the section below titled "What if I can't attend my scheduled hearing?"). No explanation is required if you are an unrepresented beneficiary or enrollee requesting to appear by VTC. For all other requests for a VTC hearing, and any requests for an in-person hearing, you must explain why you object to the type of hearing scheduled. If the Administrative Law Judge changes the type of hearing, an amended notice of hearing will be sent to the parties and any potential participants who were sent a copy of this notice.

What if I can't attend my scheduled hearing?

If you are a party to the appeal and you cannot attend the hearing at the scheduled time and place, please call our office immediately at the direct dial phone number at the top of this notice. Please *also* complete section 4 of the enclosed *Response to Notice of Hearing* and explain why you are unable to attend the hearing at the scheduled time and place. If the Administrative Law Judge finds good cause to reschedule the hearing, an amended notice of hearing will be sent to the parties and any potential participants who were sent a copy of this notice.

What if I don't attend my scheduled hearing?

If you are the appellant and neither you nor your representative appears at the scheduled hearing, the Administrative Law Judge may dismiss your request for hearing unless good cause for the failure to appear is found. If you respond to this notice of hearing and fail to appear, you must contact the Administrative Law Judge within 10 calendar days after the hearing and provide a good cause reason for not appearing. If you do not respond to this notice of hearing and fail to appear, the Administrative Law Judge will send you a notice asking why you did not appear, and you will have 10 calendar days to respond. If you do not respond to the Administrative Law Judge's notice within 10 calendar days, or you do respond and the Administrative Law Judge determines you did not have good cause for failing to appear, your request for hearing will be dismissed. If the Administrative Law Judge determines that good cause exists, the hearing will be rescheduled and the time between the originally scheduled hearing date and new hearing date will not count toward the adjudication period.

What if I don't want a hearing?

If you are a party to the appeal, you have a right to appear at the hearing to present arguments in favor of your position, and offer testimony and evidence to the Administrative Law Judge. However, if you do not wish to present your case at a hearing, you may request a decision based on the written and other evidence in the record. To do so, please complete section 4 of the enclosed *Response to Notice of Hearing*. Please also complete and submit a *Waiver of Right to an Administrative Law Judge (ALJ) Hearing* (form OMHA-104). You can find a copy of this form online at *www.hhs.gov/omha*, or you may contact our office to receive a copy. Please note

that your waiver does not affect the right of other parties to participate in the hearing and even if all parties waive the hearing, the Administrative Law Judge may still decide to conduct a hearing if it is necessary to decide the case. If a hearing is conducted and you do not attend, you may still offer written evidence to the Administrative Law Judge. Please see below for additional information regarding the submission of evidence.

What if I no longer wish to pursue this appeal?

If you decide that you no longer wish to pursue this appeal, you may withdraw your request for hearing in writing. You may do this by letter or by completing and submitting a *Withdrawal of Request for an Administrative Law Judge Hearing* (form OMHA-119). You can find a copy of this form online at www.hhs.gov/omha, or you may contact our office to receive a copy. If you submit a written request for withdrawal and no other party has filed a valid request for hearing, your appeal will be dismissed. Your request to withdraw will not be honored if a decision, dismissal or remand has already been issued.

What issues will be addressed at the hearing?

The issues before the Administrative Law Judge include all of the issues brought out in the initial determination, coverage determination, or organization determination; redetermination; or reconsideration that were not decided entirely in a party's favor, for the claims or other appealed matters specified in the request for hearing.

What if I object to the issues listed above?

If you are a party and you object to the issues, you must notify the Administrative Law Judge in writing at the earliest possible opportunity before the time set for the hearing and explain your objections. You can either do this in section 6 of the enclosed *Response to Notice of Hearing* or at a later time, but no later than 5 calendar days before the date of your scheduled hearing. You must send a copy of your objections to all the parties who were sent a copy of this notice and to CMS or any CMS contractor that has elected to be a party to the hearing. The Administrative Law Judge will make a decision on your objections either in writing, at a prehearing conference, or at the hearing.

Can I have a representative?

Yes. You have the right to have a representative attend the hearing on your behalf or attend the hearing with you. You can be represented by an attorney or other person. If you have a representative and have not completed and submitted an *Appointment of Representative* (form CMS-1696), which can be found online at www.hhs.gov/omha, or other written statement authorizing your representative to act on your behalf, please call our office as soon as possible.

Can I request a copy of the case file?

Yes. If you would like a copy of all or part of your file before the date of the hearing, please contact our office for further instructions.

Can I submit additional evidence?

If you want to submit additional written or other evidence, please complete and submit a *Filing of New Evidence* (form OMHA-115). You can find a copy of this form online at www.hhs.gov/omha, or you may contact our office to receive a copy. Unless you are an unrepresented beneficiary or enrollee, you must submit all evidence by the date (if any) you have specified in your request for hearing, or within 10 calendar days of receiving this notice. If evidence is submitted more than 10 calendar days after receiving this notice, any applicable adjudication period will be extended by the number of calendar days in the period between 10 calendar days after receipt of this notice and the day the evidence is received. Please note that although the 10-day submission time frame does not apply to unrepresented beneficiaries and enrollees, they may wish to submit any additional evidence as soon as possible to allow the Administrative Law Judge more time to consider the evidence before the hearing.

If you are a provider or supplier, or a beneficiary represented by a provider or supplier, and you are appealing a reconsideration issued by a Medicare Part A or Part B Qualified Independent Contractor (QIC), you must also submit a statement explaining why the evidence was not submitted prior to the issuance of the QIC's reconsideration. The Administrative Law Judge will determine whether you have good cause for submitting the evidence for the first time at the OMHA level of appeal.

Will any experts participate or testify at the hearing?

No experts are scheduled to testify at your hearing.

What happens at the hearing?

- The Administrative Law Judge will open the hearing and ask the parties, participants and any representatives to identify themselves and any witnesses they may be calling;
- The Administrative Law Judge will ask you and any other witnesses to take an oath or to affirm that the testimony is true;
- You will have the opportunity to present facts and arguments;
- If you are a party, you or your representative may present witnesses and may cross-examine the witnesses of the other parties;
- The Administrative Law Judge may question you and any other witnesses about the facts and issues;
- The Administrative Law Judge may allow you to submit additional written statements and affidavits about the matter in lieu of testimony or argument at the hearing. You must submit the additional statements and affidavits within the time frame designated by the Administrative Law Judge and provide a copy of them to the other parties to your hearing, if any, at the same time you submit them to the Administrative Law Judge;
- The Administrative Law Judge will review the issue(s) and entire record of your claim, independent of any determinations previously made on your claim; and
- The Administrative Law Judge will make an audio recording of the hearing.

How will I know the result of my case?

After the hearing, the Administrative Law Judge will issue a written decision, which will be mailed to all parties to the appeal, the relevant QIC or Independent Review Entity, and the Part D plan

sponsor if you are appealing a Part D coverage determination. The decision will include findings of fact, conclusions of law, and the reasons for the decision. The Administrative Law Judge will base the decision on the evidence of record, including the testimony at the hearing.

Whom do I contact with other questions about my hearing?

If you have any questions about your hearing, please call or write our office. A direct-dial telephone number and mailing address are at the top of this notice. Please provide the Administrative Law Judge name and OMHA appeal number if you write to the office, or have the information available if you call.

cc:

DEBRA M PARRISH, ESQ.
788 WASHINGTON RD
PITTSBURGH, PA 15228

NOVOCURE INC.
ATTN: JUSTIN KELLY
195 Commerce Way
Portsmouth, NH 03801

MAXIMUS

Enclosures:

OMHA-102, Response to Notice of Hearing

EXHIBIT A-3

FROM: TO:914125616253 05/14/2019 09:35:57 #053 P.002/011

Department of Health and Human Services
Office of the Secretary

19-239

OFFICE OF MEDICARE HEARINGS AND APPEALS

Arlington Field Office
2511 Jefferson Davis Highway, Suite 3001
Arlington, VA 22202
571-457-7200 (Main)
571-457-7270 (ALJ Gulin Team)
703-603-1812 (Fax)
866-231-3087 (Toll Free)

May 13, 2019

E. BANKS
128 HUNINGTON CHASE DR
MADISON, AL 35758-6921

DEBRAH PARRISH, P.C.
788 WASHINGTON ROAD
PITTSBURGH, PA 15228

NOTICE OF HEARING

Appellant:	**E. BANKS**
Beneficiary:	**E. BANKS**
Medicare Number:	*******8912A**
Date(s) of Service:	**11/12/2018–11/12/2018**
OMHA Appeal Number:	**1-8498071113**
Administrative Law Judge:	**Jeffrey Gulin**

A hearing in the above appeal is scheduled for:

Hearing Date:	**Wednesday May 15, 2019**
Hearing Time:	**10:15 am Eastern Time**

You are scheduled to appear by:
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EXHIBIT A-3

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EXHIBIT A-3

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EXHIBIT A-3

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- The Administrative Law Judge will review the issue(s) and entire record of your claim, independent of any determinations previously made on your claim; and
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EXHIBIT A-3

How will I know the result of my case?

After the hearing, the Administrative Law Judge will issue a written decision, which will be mailed to all parties to the appeal, the relevant QIC or Independent Review Entity, and the Part D plan sponsor if you are appealing a Part D coverage determination. The decision will include findings of fact, conclusions of law, and the reasons for the decision. The Administrative Law Judge will base the decision on the evidence of record, including the testimony at the hearing.

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cc:

MAXIMUS

NOVOCURE INC.
ATTN: JUSTIN KELLY
195 Commerce Way
Portsmouth, NH 03801

Enclosures:

OMHA-102, Response to Notice of Hearing

EXHIBIT A-4

FROM: TO:914125616253 05/14/2019 11:44:38 #055 P.002/011

Department of Health and Human Services
Office of the Secretary

19-314

OFFICE OF MEDICARE HEARINGS AND APPEALS

Arlington Field Office
2511 Jefferson Davis Highway, Suite 3001
Arlington, VA 22202
571-457-7200 (Main)
571-457-7270 (ALJ Gulin Team)
703-603-1812 (Fax)
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May 14, 2019

E. BANKS
128 HUNINGTON CHASE DR
MADISON, AL 35758-6921

DEBRA M PARRISH, ESQ.
788 WASHINGTON RD
PITTSBURGH, PA 15228

NOTICE OF HEARING

Appellant:	**E. BANKS**
Beneficiary:	**E. BANKS**
Medicare Number:	*******8912A**
Date(s) of Service:	**05/12/2018–05/12/2018**
OMHA Appeal Number:	**1-8501252025**
Administrative Law Judge:	**Jeffrey Gulin**

A hearing in the above appeal is scheduled for:

Hearing Date:	**Wednesday May 15, 2019**
Hearing Time:	**10:15 am Eastern Time**

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- ☒ Telephone
- ☐ Video-Teleconference (VTC)
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EXHIBIT A-4

attend the scheduled hearing, or whether you object to the proposed time and/or place of the hearing. If applicable, you must specify who else from your organization or entity plans to attend the hearing and in what capacity, and list any witnesses who will be providing testimony. If you are an employee of CMS or a CMS contractor and wish to attend the hearing as a participant, your response must indicate that you plan to attend the hearing and specify each individual who plans to attend.

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If you are a party to the appeal, you have a right to appear at the hearing to present arguments in favor of your position, and offer testimony and evidence to the Administrative Law Judge. However, if you do not wish to present your case at a hearing, you may request a decision based on the written and other evidence in the record. To do so, please complete section 4 of the

EXHIBIT A-4

enclosed *Response to Notice of Hearing.* Please also complete and submit a *Waiver of Right to an Administrative Law Judge (ALJ) Hearing* (form OMHA-104). You can find a copy of this form online at *www.hhs.gov/omha*, or you may contact our office to receive a copy. Please note that your waiver does not affect the right of other parties to participate in the hearing and even if all parties waive the hearing, the Administrative Law Judge may still decide to conduct a hearing if it is necessary to decide the case. If a hearing is conducted and you do not attend, you may still offer written evidence to the Administrative Law Judge. Please see below for additional information regarding the submission of evidence.

What if I no longer wish to pursue this appeal?

If you decide that you no longer wish to pursue this appeal, you may withdraw your request for hearing in writing. You may do this by letter or by completing and submitting a *Withdrawal of Request for an Administrative Law Judge Hearing* (form OMHA-119). You can find a copy of this form online at www.hhs.gov/omha, or you may contact our office to receive a copy. If you submit a written request for withdrawal and no other party has filed a valid request for hearing, your appeal will be dismissed. Your request to withdraw will not be honored if a decision, dismissal or remand has already been issued.

What issues will be addressed at the hearing?

The issues before the Administrative Law Judge include all of the issues brought out in the initial determination, coverage determination, or organization determination; redetermination; or reconsideration that were not decided entirely in a party's favor, for the claims or other appealed matters specified in the request for hearing.

What if I object to the issues listed above?

If you are a party and you object to the issues, you must notify the Administrative Law Judge in writing at the earliest possible opportunity before the time set for the hearing and explain your objections. You can either do this in section 6 of the enclosed *Response to Notice of Hearing* or at a later time, but no later than 5 calendar days before the date of your scheduled hearing. You must send a copy of your objections to all the parties who were sent a copy of this notice and to CMS or any CMS contractor that has elected to be a party to the hearing. The Administrative Law Judge will make a decision on your objections either in writing, at a prehearing conference, or at the hearing.

Can I have a representative?

Yes. You have the right to have a representative attend the hearing on your behalf or attend the hearing with you. You can be represented by an attorney or other person. If you have a representative and have not completed and submitted an *Appointment of Representative* (form CMS-1696), which can be found online at www.hhs.gov/omha, or other written statement authorizing your representative to act on your behalf, please call our office as soon as possible.

Can I request a copy of the case file?

Yes. If you would like a copy of all or part of your file before the date of the hearing, please contact our office for further instructions.

EXHIBIT A-4

Can I submit additional evidence?

If you want to submit additional written or other evidence, please complete and submit a *Filing of New Evidence* (form OMHA-115). You can find a copy of this form online at www.hhs.gov/omha, or you may contact our office to receive a copy. Unless you are an unrepresented beneficiary or enrollee, you must submit all evidence by the date (if any) you have specified in your request for hearing, or within 10 calendar days of receiving this notice. If evidence is submitted more than 10 calendar days after receiving this notice, any applicable adjudication period will be extended by the number of calendar days in the period between 10 calendar days after receipt of this notice and the day the evidence is received. Please note that although the 10-day submission time frame does not apply to unrepresented beneficiaries and enrollees, they may wish to submit any additional evidence as soon as possible to allow the Administrative Law Judge more time to consider the evidence before the hearing.

If you are a provider or supplier, or a beneficiary represented by a provider or supplier, and you are appealing a reconsideration issued by a Medicare Part A or Part B Qualified Independent Contractor (QIC), you must also submit a statement explaining why the evidence was not submitted prior to the issuance of the QIC's reconsideration. The Administrative Law Judge will determine whether you have good cause for submitting the evidence for the first time at the OMHA level of appeal.

Will any experts participate or testify at the hearing?

No experts are scheduled to testify at your hearing.

What happens at the hearing?

- The Administrative Law Judge will open the hearing and ask the parties, participants and any representatives to identify themselves and any witnesses they may be calling;
- The Administrative Law Judge will ask you and any other witnesses to take an oath or to affirm that the testimony is true;
- You will have the opportunity to present facts and arguments;
- If you are a party, you or your representative may present witnesses and may cross-examine the witnesses of the other parties;
- The Administrative Law Judge may question you and any other witnesses about the facts and issues;
- The Administrative Law Judge may allow you to submit additional written statements and affidavits about the matter in lieu of testimony or argument at the hearing. You must submit the additional statements and affidavits within the time frame designated by the Administrative Law Judge and provide a copy of them to the other parties to your hearing, if any, at the same time you submit them to the Administrative Law Judge;
- The Administrative Law Judge will review the issue(s) and entire record of your claim, independent of any determinations previously made on your claim; and
- The Administrative Law Judge will make an audio recording of the hearing.

EXHIBIT A-4

How will I know the result of my case?

After the hearing, the Administrative Law Judge will issue a written decision, which will be mailed to all parties to the appeal, the relevant QIC or Independent Review Entity, and the Part D plan sponsor if you are appealing a Part D coverage determination. The decision will include findings of fact, conclusions of law, and the reasons for the decision. The Administrative Law Judge will base the decision on the evidence of record, including the testimony at the hearing.

Whom do I contact with other questions about my hearing?

If you have any questions about your hearing, please call or write our office. A direct-dial telephone number and mailing address are at the top of this notice. Please provide the Administrative Law Judge name and OMHA appeal number if you write to the office, or have the information available if you call.

cc:

MAXIMUS

NOVOCURE INC.
ATTN: JUSTIN KELLY
195 Commerce Way
Portsmouth, NH 03801

Enclosures:

OMHA-102, Response to Notice of Hearing

EXHIBIT A-5

PARRISH LAW OFFICES

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April 15, 2019

VIA PRIORITY MAIL

Judge Jeffrey Gulin
Office of Medicare Hearings and Appeals
Arlington Field Office
2511 Jefferson Davis Highway, Suite 3001
Arlington, VA 22202-3087

RE: Prehearing Brief
ALJ Appeal No. 1-8428973391
Appellant/Beneficiary: E. Banks
Service: E0766
Dates of Services: 8/12/18, 9/12/18, 10/12/18
Hearing Date: To Be Determined
Our Ref. No.: 19-112

Dear Judge Gulin:

In anticipation of the scheduling of the hearing for the above-captioned case, please find attached a prehearing brief to assist in your analysis. If you have any questions regarding the foregoing, please do not hesitate to contact me at (412) 561-6250. We appreciate your consideration.

Respectfully submitted,

Debra M. Parrish
Attorney for E. Banks

Enclosures:
Prehearing Brief
CD with 2018 and 2019 studies & bibliography; Textbook Chps.

cc: Mr. Banks

ATTACHMENT A

EXHIBIT A-5

PREHEARING BRIEF – JUDGE JEFFREY GULIN
ALJ APPEAL NO. 1-8428973391
MEDICARE BENEFICIARY: EDWIN BANKS
DOS: 8/12/2018 TO 10/12/2018
HEARING DATE: TBD
April 15, 2019

A. Background

Mr. Edwin Banks, a 74-year-old retired Medicare beneficiary, former software designer, husband, father, and grandfather, was diagnosed with a glioblastoma in September 2009. His clinician prescribed chemotherapy, radiation, and surgery to treat his glioblastoma (GBM). Mr. Banks' cancer progressed in September 2013, which would indicate a recurrence of the disease. Thereafter, in December 2013, Mr. Banks was prescribed Optune to treat his GBM. The supplier submitted claims for the Optune system to the relevant Durable Medical Equipment Contractor (DMAC) which denied the claims.

The QIC denied the claims asserting "the medical documentation of the efficacy of this device is not within the usual scope and breath (sic) of current medical literature with peer acknowledgement and review." The QIC also asserted that the studies were "not non-biased" because they were supported by Novocure, and there were few clinical trials. Finally, the QIC asserted that although an LCD reconsideration request had been deemed valid, LCD L34823 has not been revised and is still in effect. As described more fully below, the denial is inconsistent with Medicare coverage criteria and the record.

1. Glioblastoma Multiforme (GBM)

Glioblastoma is the most common form of primary brain cancer, but is still very rare (~10,000 cases annually in the U.S.). The National Institutes of Health (NIH) designate glioblastoma multiforme as a rare disease, with few treatment options. See e.g., https://rarediseases.info.nih.gov/diseases/2491/glioblastoma. GBM tumors are typically highly aggressive. Survival at initial presentation is approximately 10 months, and upon recurrence, approximately 6 months, even with aggressive chemotherapy.[1] Because it is extremely rare for glioblastoma to metastasize, it is efficient to treat the disease with regional therapy as part of the treatment strategy.

2. Optune (formerly NovoTTF-100A System)

Optune, previously known as the NovoTTF-100A System, is durable medical equipment that delivers alternating electric fields or Tumor Treating Fields to the brain. The device consists of an electric field generator which is connected to four insulated transducer arrays. The arrays are placed on the patient's scalp and deliver the Tumor Treating Fields Therapy ("TTFT") to the patient's glioblastoma. Basically, the fields slow the replication of the cancer cells or stop their growth all together. The fields may also destroy some of the cancer cells.

Optune is FDA-approved for recurrent and newly diagnosed glioblastoma multiforme (GBM) brain tumors. On January 1, 2014, CMS classified the Optune device as DME requiring

[1] Rulseh et al. "Long-term survival of patients suffering from glioblastoma multiforme treated with tumor-treating fields." World Journal of Surgical Oncology at 1 (2012).

frequent and substantial servicing, which is billed under HCPCS code E0766 as a monthly rental through the duration of medical necessity. Optune has been shown to extend the lives of patients suffering from glioblastoma tumors.

B. Literature/Professional Societies

Optune is the subject of numerous peer-reviewed published studies that demonstrate the safety and efficacy of the Optune system and TTFT generally. The studies are reported in some of the most prestigious journals in our country including JAMA (the Journal of the American Medical Association). See submitted studies. Optune is included in the National Comprehensive Cancer Network (NCCN) guidelines for recurrent glioblastoma and for newly diagnosed GBM in combination with temozolomide. See submitted guidelines. The studies concluded the following:

- The final analysis of the randomized phase 3 trial (695 patients) found that the addition of Optune to standard chemotherapy treatment "resulted in statistically significant improvement in progression-free survival and overall survival" over patients that were treated with chemotherapy alone. Stupp et al. at 2315 (JAMA 2017). See also, interim analysis of 315 patients from this study (adding Optune to maintenance chemotherapy "significantly prolonged progression-free and overall survival"). Stupp et al. at 2542 (JAMA 2015).

- These important results come after a ten-year period of more than 23 randomized trials of new treatment modalities or products for glioblastoma that all "failed to demonstrate improved survival." JAMA 2017 at 2314-2315.

- Remarkably, adding Optune to traditional chemotherapy treatment "resulted in statistically significant longer deterioration-free survival in global health status, physical and emotional functioning, pain, and weakness of legs." Taphoorn et al. at E7 (JAMA Oncology 2018).

- As far back as 2012, researchers reported that in a study of 237 patients that received either Optune treatment or chemotherapy that the treatment was at least as effective as chemotherapy alone in terms of median survival, without the toxicity risks. Stupp et al. at 8-9 (European J of Cancer 2012).

The Data Safety Monitoring Board for the most recent clinical trial for glioblastoma (which included newly diagnosed and patients that suffered recurrences during the trial) found the data so compelling, they recommended early termination to allow patients who were not receiving the treatment to cross over and receive the treatment, deeming it unethical to withhold it. The FDA agreed. Please see the attached bibliography regarding TTFT which shows numerous peer-reviewed articles published on TTFT and its clinical application. Contrast the

foregoing with the exhibit list reflecting that the DMAC has not considered any of the literature or evidence that has been published in the past four years (submitted with request for hearing).

1. The QIC's assertions regarding peer-acknowledgement is belied by the evidence.

The QIC asserted, "The medical documentation in support of efficacy is not within the usual scope and breath (sic) of current medical literature with peer acknowledgement and review." Respectfully, the sentence and logic are difficult to follow. In terms of the breadth and scope of the peer-reviewed literature, a PubMed search reveals over 100 peer-reviewed articles ranging from randomized controlled trials, to case reports, to meta-analyses. The scope and breadth are particularly remarkable given the orphan status of the disease. In the past 10 years, TTFT was the only positive clinical trial and breakthrough treatment in glioblastoma. The pivotal studies were published in the Journal of the American Medical Association (JAMA), one of the most prestigious journals in the United States and one of the most cited journals in the world. Certainly, in view of the number of publications and the prestigious peer-reviewed articles that exist, it is difficult to understand the QIC's assertion that the studies do not have peer acknowledgement and review. Finally, as noted above, based on the strength of the outcomes seen, the Data Safety Monitoring Board (DSMB) recommended early termination of the clinical trial so that those in the control arm of the clinical trial could cross over and receive treatment. This was so because it would have been unethical to withhold this life-saving treatment from the control group. Thus, the effectiveness of the treatment certainly enjoyed the "acknowledgement and review" of the DSMB and the FDA.

2. The QIC's assertions regarding the clinical trials are belied by the evidence.

The QIC also asserted, "More specifically, the QIC has reviewed the peer reviewed and evidence based literature relative to clinical trials for TTFT and has found the literature and clinical trials to be limited in number and the clinical trials not non-biased; that is, the clinical trials were not independent, but funded by Novocure." Respectfully, the sentence and logic are difficult to follow. As noted above, GBM is an orphan disease with a difficult prognosis. More than one randomized controlled clinical trial was performed and reported in the peer-reviewed literature and more than 50 articles regarding TTFT for glioblastoma have been reported in the peer-reviewed literature. One of the seminal clinical trials resulted in multiple publications in the Journal of the American Medical Association, one of the most prestigious journals in the United States. On March 6, 2019, the Contractor Advisory Committee (CAC) recommended Medicare coverage of TTFT.[2] The experts found that the peer-reviewed literature shows the treatment is safe and effective. The experts did not find that the studies were limited in number or biased.

With respect to the "not non-biased" assertion, it is unclear if the QIC is attempting to assert that the manufacturer's funding of the clinical trials resulted in biased publications that

[2] See https://med.noridianmedicare.com/web/jddme/policies/lcd/contractor-advisory-committee.

could not support Medicare coverage. The studies were conducted at some of the most prestigious academic institutions in the United States by academic researchers. Most of the published clinical research on a medical intervention is sponsored in the United States. Indeed, Medicare often requires industry to sponsor certain studies as a condition of Medicare coverage. A cursory review of the literature supporting most LCDs shows that they are industry-sponsored studies. Industry sponsorship does not make a peer-reviewed study, written by academic authors, "not non-biased" such that the study cannot support Medicare coverage. If such a standard applied, Medicare would be precluded from considering most of the peer-reviewed literature published with respect to a technological advancement – an absurd result.

With respect to the number of clinical trials, Appellant notes that GBM is an orphan disease with a high mortality rate. Because the treatment is so effective, the FDA deemed it unethical to continue a study that withheld such an effective treatment from those battling a fatal disease. This is consistent with the Declaration of Helsinki, paragraph 18.[3] The CAC recognized that just as the FDA deemed it unethical to continue the clinical trial, it would be unethical to even begin more clinical studies which involved withholding a proven effective treatment for a fatal disease. A "limited number" of clinical trials is common when a treatment is proven so effective for a fatal condition. After the first study determining that a tourniquet is an effective treatment to prevent people from dying from arterial bleeding, ethically, a second study cannot be conducted. Likewise, with TTFT, given the conclusive effectiveness, additional trials that withhold the treatment cannot be conducted ethically.

C. Widespread Adoption

Based on the strength of the peer-reviewed literature and the lack of medical alternatives, the Optune system has been certified at more than 800 cancer treatment centers and has been prescribed by over 1100 physicians in 50 states, the District of Columbia, and Puerto Rico, for over 7200 patients. Virtually every major payor in the United States covers the Optune system for individuals diagnosed with a glioblastoma. These payors include, among others, Highmark, Aetna, Anthem, Humana, Kaiser, UnitedHealthcare, Cigna, Harvard Pilgrim, Geisinger, HealthPartners, and several Blue Cross plans. TTFT is used in 59 of the 62 NCI-designated cancer centers.

Indeed, support for the effectiveness and widespread adoption of the TTFT device is illustrated in CMS' assignment of a HCPCS code to the technology. When an existing HCPCS

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[3] See World Medical Association Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects: "When the risks are found to outweigh the potential benefits or when there is conclusive proof of definitive outcomes, physicians must assess whether to continue, modify or immediately stop the study." The Declaration of Helsinki finds its roots in the Nuremberg Code which required informed consent for human clinical trials after the horrific experiments conducted in concentration camps during WWII. The quoted section has been interpreted to preclude continuation of a clinical trial when effectiveness has been established for a fatal illness.

code does not adequately describe a device, a supplier applies to the HPCPS workgroup for a new HCPCS code. The code communicates relevant coverage decisions and criteria, fee schedule amounts, and billing information. In view of the criteria required to get a new HCPCS code, it is difficult for a DME device to obtain a HCPCS code. A review of the 2016-2017 DMEPOS HCPCS application summary documents reflects that only five new HCPCS codes were established although there were 63 new-code requests.[4]

For the HCPCS workgroup to award a HCPCS code for a device, CMS must have information that shows the technology (a) is deemed safe and effective by the FDA, (b) clinical studies demonstrate its use results in a significantly improved medical outcome or a significantly superior clinical outcome, (c) it is significantly functionally or therapeutically different from already-coded DME, and (d) has achieved sufficient adoption by the relevant medical community to justify the "administrative burden" of adding a new HCPCS code. Thus, CMS considers coverage criteria when awarding a HCPCS code.[5]

Finally, TTFT is so widely accepted that it is included in medical school textbooks.

D. The LCD

LCD L34823 does not reflect consideration of the required elements or provide a rationale. An LCD that on its face fails to conform to the requirements of the Medicare Program Integrity Manual, Ch. 13, is not entitled to deference. The DMAC medical directors conceded in August 2018 that the LCD was not current, and a review of the LCD exhibit list shows that the DMACs have not considered any of the scientific or clinical evidence that has evolved over the past four years.

In view of the LCD's obvious failure to reflect the peer-reviewed literature, consensus of experts, and acceptance by the relevant medical community (mandatory considerations for a valid LCD), the LCD should not be used to preclude Medicare coverage of a device that meets Medicare's coverage criteria and which is reasonable and medically necessary to treat Mr. Banks' GBM.

Notably, Administrative Law Judges are not bound by LCDs. 42 C.F.R. § 405.1062. Given the beneficiary's limited treatment options and the rarity of the disease, in addition to the compelling support for the effectiveness of the device as represented by clinical study outcomes, professional societies' statements and policies, the FDA's approval, and other payors' policies, Appellant believes the LCD should not be deferred to for Mr. Banks' claims.

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[4] Revision requests were not included in the total number of code applications. June 7, 2017 and June 8, 2017 DMEPOS HCPCS Application Summaries available at: https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCS-Application-Summaries.html.

[5] See www.ncbi.nlm.gov/PMC/articles/PMC3865619 for an article "HCPCS Coding: An Integral Part of Your Reimbursement Strategy" by Marcia Nusgart.

E. Reimbursement Amount

If Medicare coverage is found, payment for DME is made under a regulation, 42 C.F.R. §414.210(a), which states that:

> . . . *Medicare pays for [DME] . . .on the basis of 80 percent of the lesser of:*
>
> *(1) the actual charge for the item; [or]*
> *(2) the fee schedule amount for the item, as determined in accordance with §§414.220 through 414.232.*

Because no fee schedule exists, payment is 80% of the amount billed. See also Medicare Appeal Council Decision for ALJ 1-178898474.

E. Conclusion

This is the technology that clinicians treating central nervous system tumors have embraced. No basis exists to deny Medicare coverage of a device that is shown in the peer-reviewed literature to be a safe and effective treatment for glioblastoma, a life-threatening condition. The Optune system was approved as safe and effective by the FDA. The peer-reviewed literature further supports its efficacy and the improved clinical outcome of patients who use the device. It is incorporated in the NCCN guidelines (considered the gold standard for cancer care), and it enjoys widespread adoption by clinicians and all the major payors in the United States based on the foregoing. The Medicare beneficiary has no reasonable medical alternatives. The claims should be approved.

ATTACHMENT B

EXHIBIT A-5

TTFT

CD of ADD'L DOCUMENTS

- Bibliography
- 2018-2019 Publications
- Textbook Excerpts

EXHIBIT A-6

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In re LCD Complaint:
Tumor Treatment Field Therapy
LCD ID Number: L34823
Contractor: CGS Administrators, LLC

Docket No. C-19-396

Date: May 28, 2019

ORDER REGARDING DISCOVERY AND ADDITIONAL EVIDENCE

Om May 20, 2019, CGS Administrators, LLC (CGS) filed its "Contractor's Response to the Aggrieved Party's Statement Regarding the LCD Record, Motion to Strike the LCD as Invalid, and Motion to Supplement Complaint (CGS response). Under the regulations, the next step is for me to evaluate the evidence that has been submitted and determine if "the LCD record is complete and adequate to support the validity of the LCD" under the reasonableness standard. 42 C.F.R. § 426.425(c)(1). For the reasons stated below, I conclude that the record presently is insufficient to support the validity of the challenged provision in LCD L34823. As a result, I order the parties to indicate whether they want me to close the record in this case or whether they want to engage in discovery or otherwise provide me with additional evidence. 42 C.F.R. § 426.425(c)(3).

I. The LCD's record does not support the LCD's validity.

After I accepted the Aggrieved Party's Complaint in this matter, in conformance with the regulations governing this case, I ordered CGS to file the LCD record, the Aggrieved Party to file a statement explaining why the LCD is not valid, and CGS to file a response defending the LCD. *See* 42 C.F.R. §§ 426.410(d)(3), 426.425(a)-(b). The parties have completed their submissions. I have reviewed the submissions and conclude that the LCD record is insufficient to support the LCD's categorical denial of coverage for tumor treatment field therapy (E0766) (TTFT).

A. The Aggrieved Party has standing to challenge the LCD.

CGS indicated that the Aggrieved Party's "LCD complaint is inapplicable as binding to the [Medicare Advantage] Plan" because Medicare Advantage Plans "have the option of providing individualized care if desired . . . and thus, are not bound to cover only Medicare-covered services." CGS Response at 1. Although not entirely clear, CGS appears to be challenging the Aggrieved Party's standing to challenge the LCD.

If this is the case, CGS is mistaken in its argument because an "Aggrieved party" includes enrollees in Medicare managed care plans so long as coverage for a service was denied based on the challenged LCD. 42 C.F.R. § 426.110. The Aggrieved Party meets these requirements. A. Ex. 8 at 5-6. Therefore, the Aggrieved Party has standing to challenge the LCD. 42 C.F.R. § 426.320(a).

B. An Aggrieved Party may challenge an LCD because it is outdated.

CGS asserted that the LCD record shows that the LCD was valid at the time the LCD was adopted. CGS further indicated that there is a reconsideration process for revising LCDs in the Medicare Program Integrity Manual, Chapter 13. CGS then concluded that "[n]either the relevant Statutes, Federal rules and regulations, nor sub-regulatory guidance issued by [the Centers for Medicare & Medicaid Services (CMS)] contemplated the role of an LCD Challenge as an alternate pathway for an LCD Reconsideration." CGS Response at 3-4, 7.

CGS misunderstands both the LCD challenge process and how it relates to the LCD reconsideration process. Congress established LCDs and provided some basic requirements related to the development of LCDs. 42 U.S.C. § 1862(*l*)(5). However, Congress also established an LCD review process, to be conducted by an administrative law judge (ALJ). 42 U.S.C. § 1395ff(f)(2). This process is meant to determine the validity of the LCD. *Id.* § 1395ff(f)(2)(i)(I). In promulgating the regulations to implement this process to challenge an LCD, the Secretary of Health and Human Services (Secretary) made it clear that the process for challenging the validity of an LCD may be invoked because "a challenger may believe that a policy that was correct when it was issued has become outdated and is no longer valid in light of advances in medicine." 68 Fed. Reg. 63,692, 63,700 (Nov. 7, 2003). In fact, the Secretary expressly permitted aggrieved parties to submit new evidence concerning the LCD so that the ongoing validity of the LCD could be tested. *Id.*; *see also* 42 C.F.R. § 426.403.

Further, the Secretary was fully aware of the LCD reconsideration process and provided procedures by which the contractor or the ALJ could evaluate whether new evidence submitted in the case warranted a reconsideration of the LCD. 42 C.F.R. §§ 426.340, 426.417. As stated in the preamble to the final rule:

EXHIBIT A-6

> We have modified the procedures at § 426.340 to allow the ALJ/Board to make a preliminary determination on whether the new evidence submitted would have a significant bearing on the validity of the LCD/NCD. If the evidence is found significant, it would be sent to the contractor/CMS to determine whether the contractor/CMS agrees that the evidence warrants a formal reconsideration. As mentioned earlier, the reconsideration process would be time limited but would allow the public to submit medical and scientific evidence and allow the agency to fully develop the record in light of advances in medical science. Following the time-limited reconsideration, a supplemental record would be filed and the adjudication could continue, if necessary.
>
> This approach will provide the contractor/CMS the initial opportunity to permit medical and scientific experts to examine the new evidence and to make findings of fact concerning the new evidence. Among other things, the statute requires that the ALJ/Board "shall defer only to the reasonable findings of fact" and it was impossible for the agency to have made findings on evidence that did not yet exist or that had not been furnished to the agency for consideration. We believe this approach is necessary to ensure that the medical and scientific opinions of the agency experts illuminate the record, since these appeals could involve very technical medical and scientific material related to the new evidence.

68 Fed. Reg. at 63,700. The Secretary knew that the LCD review process and reconsideration processes are different. The preamble to the final rule stated:

> **5. Differences Between an LCD/NCD Review and an LCD/NCD Reconsideration**
>
> The main difference between an LCD/NCD review under section 522 of the BIPA and an LCD/NCD reconsideration is the avenue an individual chooses to take to initiate a change to a coverage policy and who may initiate the review. All interested parties, including an aggrieved party, may request a reconsideration of an LCD or NCD, rather than filing a complaint to initiate the review of an LCD or NCD. Conversely, only an aggrieved party may file a complaint to initiate the review of an LCD or NCD. If the aggrieved party

> believes that we, or the contractor, misinterpreted evidence or excluded available evidence in making the coverage determination or has new evidence to submit, then the aggrieved party has the option to file a request for a reconsideration by the contractor or us, respectively, or to file a complaint to seek review by an adjudicator.
>
> In the reconsideration process, all interested parties, not just aggrieved parties, have the opportunity to submit new scientific and medical evidence for review by individuals with medical and scientific expertise. The reconsideration process permits experts to make judgments about those policies, rather than using an adjudicatory proceeding.

68 Fed. Reg. at 63,694. Another major distinction between the LCD review process before an ALJ and the reconsideration process before a contractor is that an ALJ can only decide that an LCD provision is no longer valid, but cannot revise the LCD provision. 42 C.F.R. §§ 426.405(d)(14), 426.450(a)(2).

C. The LCD's record is inadequate to support the validity of the LCD.

CGS filed the record of the LCD in this case. The LCD was published in 2015, and the entire LCD record consists of documentation and reports from that time and earlier. However, the Aggrieved Party has submitted many documents and reports that more recently show the efficacy of TTFT, at least within certain parameters. Significantly, the Aggrieved Party has submitted 21 out of the 29 reports and journal articles that CGS has considered in the reconsideration process that CGS has already started. A. Exs. 5-6, 12, 70-72, 82, 95, 122-123, 125, 129, 136-137, 139, 143, 146, 150, 155, 157, 158; CMS Ex. 43 at 10-13. Further, based on these documents, CGS, along with other Medicare contractors, have proposed to remove the categorical prohibition on coverage of TTFT to permit coverage if specific criteria are met. CMS Ex. 44.

II. The parties may request to engage in discovery and submit additional evidence.

The regulations state:

> If the ALJ determines that the LCD record is not complete and adequate to support the validity of the LCD, the ALJ permits discovery and the taking of evidence in accordance with §§426.432 and 426.440 and evaluates the LCD in accordance with §426.431.

42 C.F.R. § 426.425(c)(3).

EXHIBIT A-6

In the present case, the Aggrieved Party appears likely to have submitted all of the evidence it plans to submit and CGS has already indicated that it neither plans to submit written direct testimony for any witnesses nor cross-examine the Aggrieved Party's witnesses. However, the parties will indicate by **June 5, 2019**, if they want to pursue discovery or to submit additional evidence.

Further, if the parties have objections to any of the exhibits submitted thus far by the other party, written objections must be submitted by **June 5, 2019**.

When the evidentiary record closes in this case, I will next need to determine whether the new evidence in the record is significant and permit CGS an opportunity to conduct a reconsideration. 42 C.F.R. § 426.340.

S Anderson

Scott Anderson
Administrative Law Judge

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